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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,464	05/24/2001	Saverio C. Falco	BB1193 USDIV	3016

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,464

Applicant(s)

FALCO ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-66 is/are pending in the application.
- 4a) Of the above claim(s) 44-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-34 is/are rejected.
- 7) ☒ Claim(s) 35-43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (mailed on November 28, 2003), Applicants filed responses and amendments received on May 27, 2004 and August 23, 2004. Said amendments amended Claims 31-34 and 37-43. Thus, Claims 31-66 are pending in the instant Office action. Claims 44-66 remain withdrawn from consideration as non-elected inventions (without traverse and not subject to rejoinder, thus their cancellation is suggested). Claims 31-43 will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/864,464 filed July 20, 1999 (divisional parent) and for U.S. Provisional Application No. 60/093,530 filed July 21, 1998.

Information Disclosure Statement

3. The information disclosure statement filed on May 27, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copies. The page that has not been considered is comprises solely of duplicate citations found elsewhere in the IDS in more complete fashion. Moreover, Applicant is encouraged in the future to not "re-file" a PTO-892 since it can confuse the record as being cited by the Examiner and not Applicant as is the case here.

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Oath/Declaration

4. Previous holding that the declaration was defective is withdrawn by virtue of Applicant's arguments. No date of execution of the oath is required (see M.P.E.P. § 602.05).

Withdrawn - Objections to the Specification

5. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title (the amendment to page 1, line 2). Applicant's amendment to page 33 is unclear; however, since the specification only has 28 pages; said amendment to page 33 has thus not been entered.

6. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Objections

7. Previous objection to Claim 31 for using an improper article is withdrawn by virtue of Applicant's amendment on May 27, 2004.
8. Previous objection to Claims 31-34 for improperly limiting % identity between sequences is withdrawn by virtue of Applicant's amendment on August 23, 2004.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 37-40 and 42-43 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "the polynucleotide of claim 31" or "the chimeric gene of claim 37" (emphasis added) is withdrawn by virtue of Applicant's amendment.

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10. Previous rejection of Claim 41 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of “the chimeric gene of claim 31” is withdrawn by virtue of Applicant’s amendment.

Maintained - Claim Rejections - 35 U.S.C. § 112

11. Previous rejection of Claims 31-34 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide that encodes SEQ ID NO:10, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the 80% identity claimed is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that Arnez *et al.* and Desogus *et al.* teach common and distinguishing characteristics for class II aminoacyl tRNA synthetases. While this may be true, the claims are drawn to lysyl tRNA synthetase (tRS), not generically class II aminoacyl tRSs. Furthermore as argued by Applicant, Girtch *et al.*, as previously identified by the Examiner, does teach an alignment among lysyl tRSs from various sources; the “highly conserved motifs” account for only about 10% of the overall protein. The relationship among plant Lys-tRSs as shown in Applicant’s Appendix A represents more clearly that these motifs, while conserved, represent only about 5% overall identity of the protein in plants. Additionally, the claims are not limited to plant sequences but to any protein displaying Lys-tRS activity. The overall sequence relatedness to Lys-tRS from human to these plant sequences is about 60%.

Furthermore, proteins are three-dimensional structures and the interactions of these motifs with other portions of the protein are also important. In the instant case, a variability of 80% in the protein sequence allows about 127 residues of the 634 amino acid protein to be

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varied. Wherein only a small portion of the overall protein sequence has been shown to be conserved, this much variability is not supported by the art, despite the extensive information of sequence similarity and even three-dimensional structure.

Moreover, the instant claims are not limited to class II Lys-tRSs. It is known that both class I and class II Lys tRSs exist and that they are structurally dissimilar (see Terada *et al.* Functional convergence of two lysyl-tRNA synthetases with unrelated topologies. Nature Structural Biology (2002) 9:257-262).

For all these reasons, the breadth of the instant claims is not enabled to the full extent of its scope because one of skill in the art would be unable to make all the members of the genus, wherein lysyl tRS activity is required for the encoded protein, to the extent of 80% identity to SEQ ID NO:10. However, due to the extensive showing of the knowledge in the art both by Applicant and in the Examiner's notes, claims drawn to polynucleotides encoding polypeptides at least **90% identical** to SEQ ID NO:10 wherein the polypeptides are **class II** lysyl tRNA synthetases would be considered **allowable** to the full extent of that breadth. *Such limitations would be considered after final by the Examiner.*

Summary of Pending Issues

12. The following is a summary of the issues pending in the instant application:

- a) Claims 35-43 stand objected to for depending from a rejected claim.
- b) Claims 31-34 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Closest Prior Art

13. As previously noted, the closest prior art to the claimed invention is found in genes encoding lysyl-tRNA synthetases from other plants. The gene from *A. thaliana* (GenBank

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Accession Number AF125574) encodes a protein that is 69% identical to SEQ ID NO:10; the gene from *L. esculentum* (GenBank Accession Number X94451) encodes a protein that is 63% identical. Thus, the claimed invention is free of the prior art. The Examiner notes, however, that the starting amino acid is a leucine, not a methionine – thus, whether or not the gene in SEQ ID NO:9 is a full-length gene is unclear. The two known plant sequences are 602 and 588 amino acids long. Thus, SEQ ID NO:10, having 634 amino acid residues, appears to be well within the range of a full-length protein, such that lysyl-tRNA synthetase activity could be expected.

Conclusion

14. Claims 31-34 are rejected and Claims 35-43 are objected to for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

November 13, 2004